

REMARKS

In the Office Action dated April 26, 2006, the United States Patent & Trademark Office (USPTO) rejected claims 1-5, 8-9, 12, 14 and 16-27 under 35 U.S.C. § 103(a) based upon U.S. Patent No. 5,282,844 issued to Stokes in view of U.S. Patent No. 6,287,285 issued to Michal.

Claim 1 is directed to an implantable therapy delivery and / or diagnostic device. The diagnostic device includes "a fixation element adapted to secure the device to an implant site...one or more elongate conductors extending within the device...a polymeric layer overlaying a portion of the device in proximity to the implant site and including an outer surface... and a layer of a catalytic agent, having nitrite reductase and / or nitrate reductase, or nitrosothiol reductase activity, present on the outer surface of the polymeric layer." "[T]he catalytic layer converts nitrite/nitrate or nitrosothiols to nitric oxide when in contact with blood." Stokes relates to an implantable medical lead. The USPTO concedes that Stokes does not include a layer of catalytic agent. Instead, the USPTO relies upon the teachings of Michal. Michal relates to a dilation catheter to deliver a therapeutic drug. Michal also discloses the use of nitric oxide donor drugs such as nitric oxide-polyamine complexes, 2-methyl-2-nitrosopropane, S-Nitroso-N-acetyl-D,L-penicillamine, 3-morpholinoxydoimine, sodium nitrate, s-nitrosoglutathione, sodium nitroprusside, and nitroglycer. The USPTO asserts that nitric oxide donor drugs inherently involve nitrite reductase, nitrate reductase, or nitrosthiol reductase activity.

The Applicant disagrees and challenges all of the USPTO's inherency arguments. Michal introduces nitric oxide donor drugs to a patient's body. The nitric oxide is formed from these drugs after the drug chemically reacts. The nitric oxide is released from these compounds and that a catalyst is unnecessary for this operation. In contrast, Applicant's claimed invention uses precursors from the blood stream along with the layer of catalytic agent in order to form nitric oxide. If the USPTO continues to reject Applicant's claims, the Applicant

respectfully requests that the USPTO support its assertions that a catalyst is inherent to Michal.

Claims 6 and 10 are rejected under 35 U.S.C. § 103(a) based upon Stokes in view of Michal and further in view of U.S. Patent Application No. 2001/0018607 by Borgerson. Claims 7, 11, and 13 are also rejected under 35 U.S.C. § 103(a) based upon Stokes in view of Michal and Borgerson and further in view of U.S. Patent No. 5,861,023 to Vachon. None of the cited references cure the deficiency noted with Michael. Withdrawal of the instant rejections and issuance of a Notice of Allowance is respectfully requested.

Respectfully submitted,

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Date

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